U.S. Application No. 10/598,518
Response to Office Action mailed March 13, 2009

#### **REMARKS**

After entry of the foregoing amendment, claims 14-19, 21, 23 and 30-44 are pending. Claims 1-13 and 24-29 are cancelled herein. Claims 20 and 22 were previously cancelled. Claims 14, 18, 19, 21, 23 and 30 are amended. Claims 35-44 are newly added herein.

Claim 14 has been amended to be directed to novel imine and carbinolamine pyrrolobenzodiazepine dimers. New claim 35 is directed to protected forms of the novel compounds. Both of these claims find basis in previous claim 14 as well as in the specification at page 5, lines 17 to 19 and from page 40, line 33 to page 41, line 2.

New claims 39 to 43, further define the groups R<sup>9</sup>, R<sup>6</sup>, R<sup>7</sup> and R<sup>15</sup>. These can be found in the description from page 39, line 26 to page 40, line 7 and at page 41, lines 4 to 14. The optional substituents are detailed in the specification at pages 8 to 24.

New claim 44 defines each of the substituents in a novel compound of claim 14, defining the structure ZC 207 found in the description at page 55, line 15. New claims 36 and 37 define specific protecting groups, as disclosed on page 40, lines 21 to 23.

New claim 38 corresponds to a narrowed version of previous claim 1, and to the specification from page 3, line 18 to page 4, line 15 and from page 40, line 33 to page 41, line 2. It refers to novel intermediates for use in the synthesis of the novel compounds of claims 14 and 35.

Amended claim 30 defines a key step in the synthesis of the dimers of claims 14 and 35 from the intermediates of claim 38. The step is explained in the specification from page 38, line 11 to page 39, line 5.

Claims 31 to 34 set out specific conditions for the key step in the synthesis. They correspond to the section of the specification from page 38, line 15 to page 39, line 1.

Claims 18, 19, 21 and 23 have been amended to depend from a non-cancelled claim. Claim 23 was also amended to claim method of treating leukemia. Support for this amendment may be found at least in Example 9 on page 73-74. Claims 14 and 30 have been amended to further define the optional substitutents. Support for these amendment may be found at least at page 8, line 1 to page 22, line 31.

## Rejections Under Section 112, Second Paragraph

Claims 1-19, 21 and 23-24 were rejected under 35 U.S.C. § 112, second paragraph as indefinite for various reasons. First, the claims were rejected for the use of "salts and solvates thereof." Applicants have deleted this term and therefore request that the rejection be withdrawn.

The claims were also rejected because the terms "carbamate-based nitrogen protecting group" and "oxygen protecting group" were thought to be unclear where the compounds were final products. As discussed above, certain of the claims are directed to intermediates in which it is reasonable to have protecting groups. Other claims are directed to final products which are not defined as protected. In addition, claim 35 is directed to protected forms of the novel imine and carbolamine pyrrolobenzodiazepine dimers. Applicants are entitled to claim protected forms of the novel compounds. These protected forms may be present as intermediates in the synthesis of the compounds. One of ordinary skill in the art would be able to determine suitable protecting groups based on the specification and claims.

Additionally, the claims were rejected for the use of the term "optionally substituted." Applicants have amended the claims to further define the substituents and request that the rejection be withdrawn.

The claims were rejected for the use of the terms " $C_{3-20}$  heterocyclyl" and " $C_{5-20}$  aryl." Applicants respectfully submit that these terms are fully defined in the specification at page 10, line 3 to page 11, line 8 ( $C_{3-20}$  heterocyclyl) and page 11, line 10 to page 12, line 36 ( $C_{5-20}$  aryl). It is entirely proper for Applicants to define these terms in the specification. "An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s)." MPEP 2111.01. Applicants have done just that here. Therefore, Applicants request that the rejection be withdrawn.

Claims 24 and 30 were also rejected as being incomplete for omitting essential steps. Applicants have cancelled claim 24 and amended claim 30 to further define the reaction steps and request that the rejection be withdrawn.

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# Rejections Under Section 112, First Paragraph

Claims 1-19, 21 and 23-34 were rejected under 35 U.S.C. 112, first paragraph as not being enabled for solvates of the claimed compounds. Applicants have amended the claims to delete the term "solvates" and request that the rejection be withdrawn.

Claim 23 has also been rejected as not enabled for the treatment of a proliferative disease generally. Claim 23 has been amended to claim a method of treating leukemia. Applicants respectfully submit that claim 23, as amended, is adequately enabled by the specification. In Example 9, Applicants show that compounds according to the present invention have cytotoxicity against leukemia cells. Therefore, Applicants request that the rejection be withdrawn.

## Rejections Under Section 102

Claims 1, 11 and 14 were rejected as anticipated by Ueda et al. (U.S. Patent No. 4,309,437) or Leingruber et al. (U.S. Patent No. 3,523,941). The present claims are directed to compounds have a  $C_{5-20}$  aryl group at the 2-position. Neither of the cited references discloses compound with a  $C_{5-20}$  aryl group at the 2-position. Therefore, Applicants respectfully request that the rejection be withdrawn.

### CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance. Should the examiner feel that further discussion is warranted, the examiner is invited to contact the undersigned at the number below.

Respectfully submitted,

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